OLYMPUS®

INSTRUCTIONS

OLYMPUS
EndoTherapy

MECHANICAL LITHOTRIPTOR

BML-3Q-1

BML-4Q-1

USA: CAUTION: Federal law restricts this device to sale by or on the order of a physician.	CE 0197

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Symbols

The meaning(s) of the symbol(s) shown on the package, the back cover of this instruction manual and/or this instrument are as follows:

Refer to instructions.

Single use only

Use by (expiration date)

Sterilized using ethylene oxide

Sterilization lot number

Lot number

Manufacturer

Authorised representative in the European Community

Important Information–Please Read Before Use

Intended Use

These instruments have been designed to be used with an Olympus endoscope for crushing calculi inside the bile duct. Do not use these instruments for any purpose other than their intended use.

Instruction Manual

This instruction manual contains essential information on using this instrument safely and effectively. Before use, thoroughly review this manual and the manuals of all equipment which will be used during the procedure and use the instruments as instructed.
Keep this and all related instruction manuals in a safe, accessible location.
If you have any questions or comments about any information in this manual, please contact Olympus.

User Qualifications

The operator of this instrument must be a physician or medical personnel under the supervision of a physician and must have received sufficient training in clinical endoscopic technique. This manual, therefore, does not explain or discuss clinical endoscopic procedures.

Instrument Compatibility

Refer to the Table in Section 2.2, “Specifications” to confirm that this instrument is compatible with the ancillary equipment being used. Using incompatible equipment can result in patient injury and/or equipment damage.

Reprocessing and Storage

The Basket Wire was shipped in a sterile condition. Store it following the instructions in Chapter 6, “Storage”. Improper storage can present an infection control risk, cause equipment damage or reduce performance.

The Basket Wire is a single-use, disposable item that is not to be reprocessed. Do not reuse or attempt to sterilize it. The Coil Sheath, the Tube Sheath and the BML Handle were not sterilized before shipment. Before using the Coil Sheath, the Tube Sheath and the BML Handle for the first time, reprocess them according to the instructions in Chapter 5, “Reprocessing”.

After using the Coil Sheath, Tube Sheath and BML Handle, reprocess and store them according to the instructions in Chapter 5, “Reprocessing” and Chapter 6, “Storage”. Improper and/or incomplete reprocessing or storage can present an infection control risk, cause equipment damage or reduce performance.

Repair and Modification

This instrument and BML Handle do not contain any user-serviceable parts. Do not disassemble, modify or attempt to repair them; patient or user injury and/or equipment damage can result.

Signal Words

The following signal words are used throughout this manual:

WARNING Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

CAUTION Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practices or potential equipment damage.

NOTE Indicates additional helpful information.

Warnings and Cautions

Follow the warning given below when handling this instrument and the BML Handle. This information is to be supplemented by the warnings described in each chapter.

WARNING

- Before use, thoroughly review the method of use for this instrument and BML-110A-1 in accordance with the instruction manuals.
- Do not use this instrument for a calculus that is assumed impossible to be crushed by a lithotriptor. The pipe or the basket wire may break and part of this instrument may remain in the body.
- Use this instrument by having the settings to switch to open surgery and the hospitalization plan ready in case the calculus cannot be crushed by lithotriptor BML-110A-1.

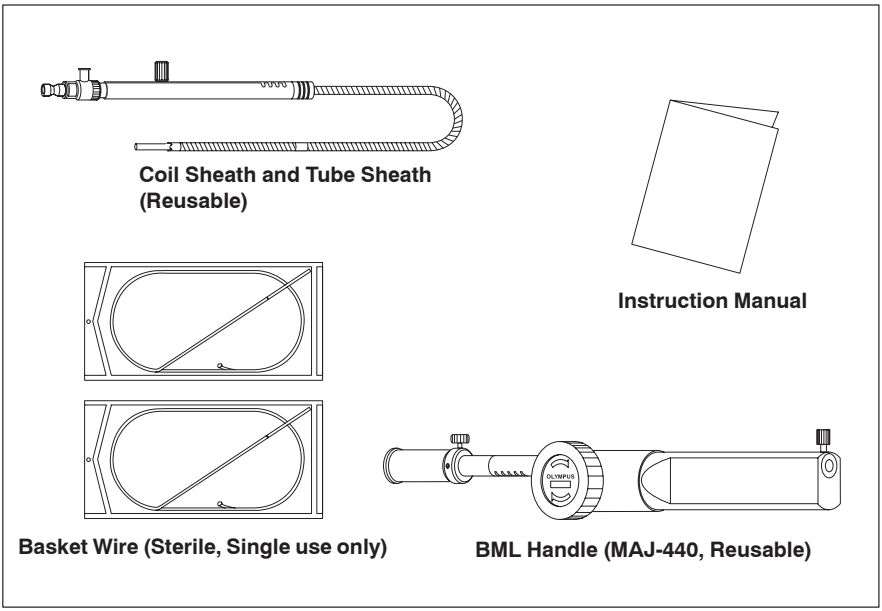
- A Lithotriptor cannot always crush all calculi captured in the Basket. Operation of this instrument is based on the assumption that open surgery is to be possible as an emergency measure. If the calculus is too hard, there is possibility that the damages shown in Chapter 4 “Emergency Treatment” may occur. Use this instrument by considering that it may lead to damaging the instrument and that open surgery may have to take place.

Chapter 1 Checking the Package Contents

1.1 Checking the Package Contents

Match all items in the package with the components shown below. Inspect each item for damage. If the instrument or the BML Handle is damaged, a component is missing or you have any questions, do not use the instrument or the BML Handle; immediately contact Olympus.
The Coil Sheath, the Tube Sheath and the BML Handle were not sterilized before shipment. Before using the Coil Sheath, the Tube Sheath and the BML Handle for the first time, reprocess them according to the instructions in Chapter 5, “Reprocessing”.

❍ A set



B set

Coil Sheath (Reusable, 1 piece)

Tube Sheath (Reusable, 1 piece)

Basket Wire (Sterile, single use only, 2 pieces)

Instruction Manual

Coil Sheath

Coil Sheath (Reusable, 1 piece)

Tube Sheath

Tube Sheath (Reusable, 1 piece)

Basket Wire

Basket Wire (Sterile, single use only, 1 piece)

BML Handle

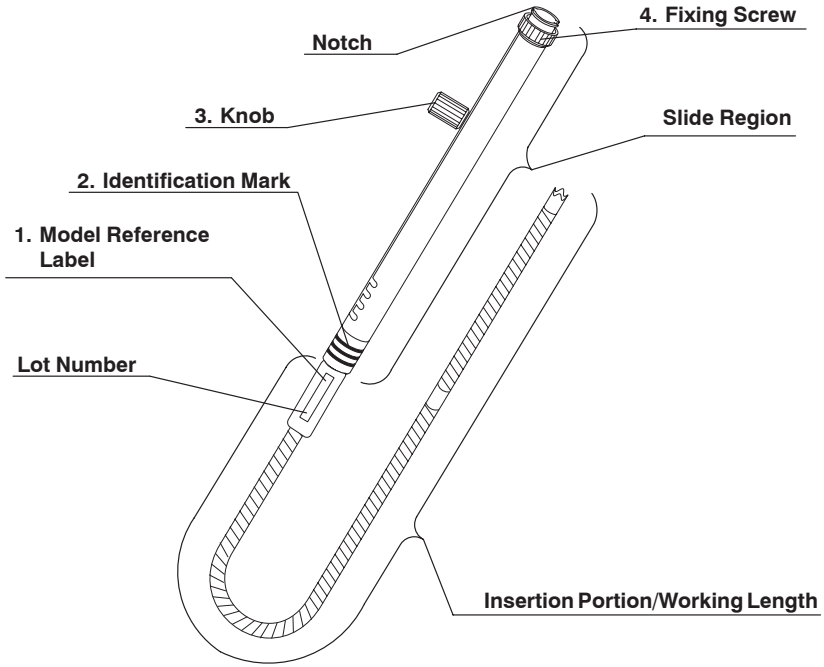
BML Handle (MAJ-440, reusable, 1 piece)

Chapter 2 Instrument Nomenclature and Specifications

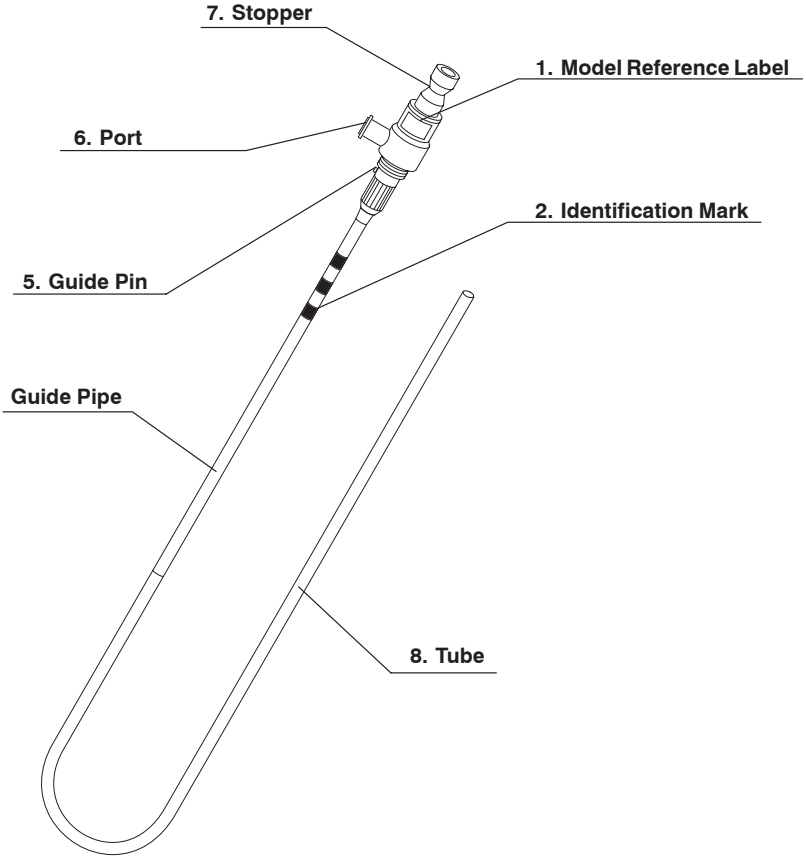
2.1 Nomenclature and Functions

This instrument consists of a Coil Sheath, Tube Sheath and Basket Wire. The Tube Sheath is inserted into the Coil Sheath and the Basket Wire is inserted into the Tube Sheath prior to use.
This instrument must be used in combination with the BML Handle.

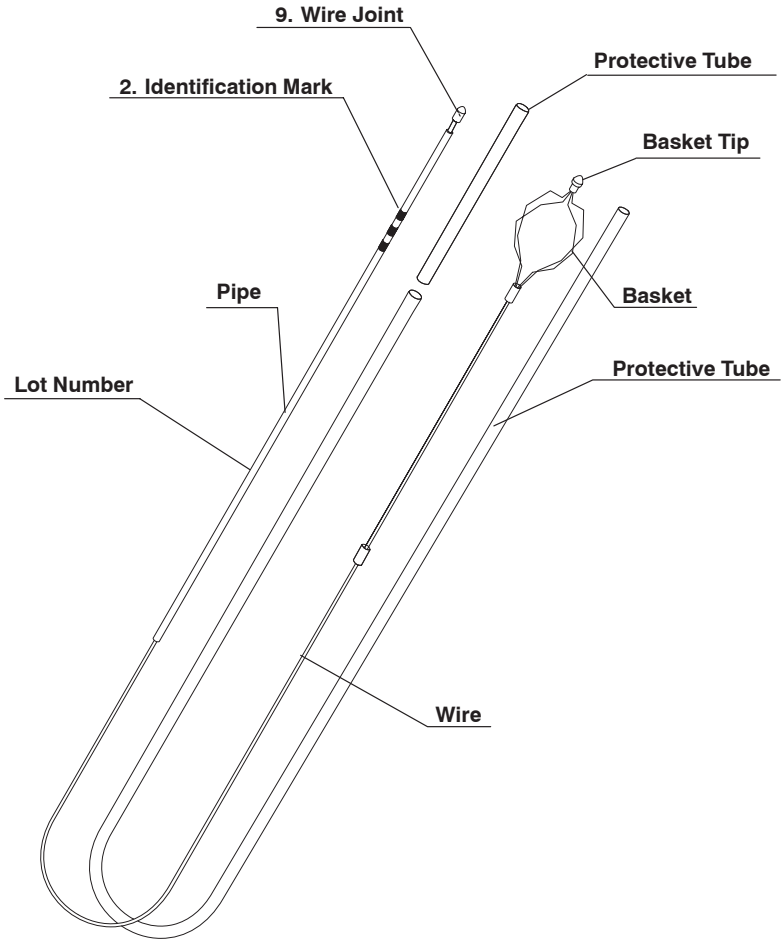
❍ Coil Sheath (Reusable)



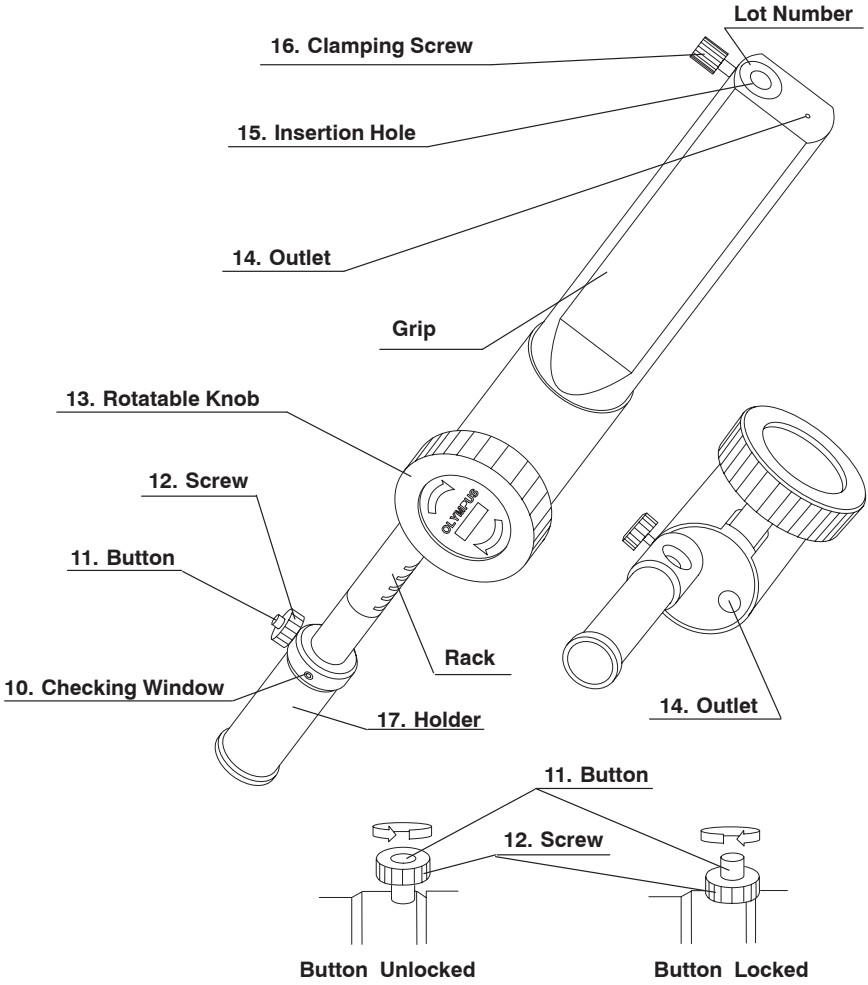
◕ Tube Sheath (Reusable)



❍ Basket Wire (Sterile, Single use only)

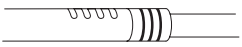
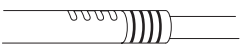
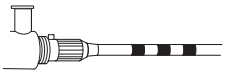


BML Handle (MAJ-440, Reusable)



1. **Model Reference Label**
Indicates the product number.
A green reference label indicates that the instrument is autoclavable.

2. **Identification Mark**
The Coil Sheath, Tube Sheath and Basket Wire are marked as follows for each model.

Model	BML-3Q-1	BML-4Q-1
Coil Sheath	Side Region 3 black stripes 	Side Region 4 black stripes 
Tube Sheath	Guide Pipe 3 black stripes 	Guide Pipe 4 black stripes
Basket Wire	Pipe 3 black stripes 	Pipe 4 black stripes

3. **Knob**
Used to slide the Coil Sheath. Locks the position of the Slider Region when tightened.

4. **Fixing Screw**
Secures the Tube Sheath when tightened.

5. **Guide Pin**
Aligned with the Notch at the proximal end of the Coil Sheath to properly align the Coil Sheath with the Tube Sheath.

6. **Port**
Attach a syringe here to inject contrast medium (BML-3Q-1 only) or flush reprocessing chemicals, water and air through the Tube Sheath when reprocessing (BML-3Q-1 and BML-4Q-1).

7. **Stopper**
Attached to the BML Handle.

8. **Tube**
On the BML-3Q-1, works as the channel through which contrast medium is injected during use. It also works as the channel through which reprocessing chemicals, water or air are flushed to the distal end when reprocessing.

9. **Wire Joint**
Attached to the Holder of the BML Handle. If the Wire Joint has groove on it, the handling, operating and maintenance procedures described in this manual are applicable.

10. **Checking Window**
Allows user to view the Wire Joint when attaching it to the Holder of the BML Handle.

11. **Button**
Secures and releases the Wire Joint of the Basket Wire.

12. **Screw**
Turn the Screw to lock and unlock the Button.

13. **Rotatable Knob**
When turned, the Basket is gradually retracted in order to crush the calculi.

14. **Outlet**
Discharge the remaining lubricant from here when reprocessing.

15. **Insertion Hole**
The Basket Wire's Pipe and the Tube Sheath's Stopper are inserted here.

16. **Clamping Screw**
Tightened to secure the Stopper of the Tube Sheath.

17. **Holder**
Moved back and forth to open and close the Basket when the BML Handle is connected to the instrument.

2.2 Specifications

The compatible Olympus endoscopes are listed in the Table on the following page. New endoscopes released after the introduction of this instrument and BML Handle may also be compatible for use in combination with this instrument and BML Handle. For further details, contact Olympus.

WARNING Use this instrument and BML Handle only in combination with products recommended by Olympus. If combined with products not recommended by Olympus, patient or operator injury, malfunction and/or equipment damage may result.

Operating Environment

Ambient Temperature	10 to 40°C (50 to 104°F)
Relative Humidity	30 to 85%
Air Pressure	700 to 1060 hPa (0.71 to 1.08 kgf/cm^2) (10.1 to 15.4 psia)

Specifications

The recommended Coil Sheath, Tube Sheath and Basket Wire combinations for each instrument are as follows:

WARNING Do not use the Coil Sheath, Tube Sheath or Basket Wire in combinations other than those listed below. An incorrect combination could cause patient injury and/or equipment damage.

Product Name	**BML-3Q-1**	**BML-4Q-1**
Coil Sheath	MAJ-242	MAJ-245
Tube Sheath	MAJ-243	MAJ-246
Basket Wire	MAJ-244	MAJ-247

Model		**BML-3Q-1**	**BML-4Q-1**
Shape of the Grasping Basket			
Maximum Insertion Portion Diameter (mm)		ø 3.7	ø 2.9
Working Length (mm)		1950	
Opening Length (mm)		30	
Compatible Olympus Endoscopes (All of the parameters should be met.)	**Model and Length**	Working Length less than 1400 mm; TJF	Working Length less than 1400 mm; JF, TJF
	Channel Inner Diameter (mm) (Color Code)	ø 4.2 (Orange); ø 5.5 (Pink)	ø 3.2 (Yellow); ø 4.2 (Orange); ø 5.5 (Pink)
Compatible Olympus Handle		BML Handle: MAJ-440	
Compatible Olympus Lithotriptor for Emergency Use		BML-110A-1	

Medical Device Directive	CE 0197	This device complies with the requirements of Directive 93/42/EEC concerning medical devices. Classification: Class I

Chapter 3 Preparation, Inspection and Operation

The Basket Wire was shipped in a sterile condition.
The Coil Sheath, the Tube Sheath and the BML Handle were not sterilized before shipment.

WARNING

- Do not use the Basket Wire after the expiration date displayed on the sterile package. Doing so may pose an infection control risk and/or cause tissue irritation.
- When using the instrument and the BML Handle, always wear appropriate personal protective equipment, Otherwise, blood, mucous and other potentially infectious material from the patient could pose an infection control risk. Appropriate personal protective equipment may include: Eye wear, a face mask, moisture-resistant clothing and chemical-resistant gloves, that fit properly and are long enough so that your skin is not exposed.

- Before each case, prepare and inspect the instrument and the BML Handle as instructed below. Inspect other equipment to be used with the instrument and the BML Handle as instructed in their respective instruction manuals.
  Should the slightest irregularity be suspected, do not use the instrument or the BML Handle; contact Olympus. Damage or irregularity may compromise patient or user safety, since it may pose an infection control risk, cause tissue irritation, punctures, hemorrhages or mucous membrane damage. It may also result in more severe equipment damage.
- The coil Sheath, the Tube Sheath and the BML Handle were not sterilized before shipment. Before using the Coil Sheath, the Tube Sheath and the BML Handle for the first time, reprocess and assemble them according to the instructions in Chapter 5, “Reprocessing”.
  Do not use an instrument or the BML Handle that has not been cleaned and sterilized. This could pose an infection control risk and/or can cause tissue irritation.

CAUTION

- Do not coil the Insertion Portion with a diameter of less than 15 cm. This could damage the Insertion Portion.
- Never use excessive force to operate the instrument and the BML Handle. This could damage the instrument and/or the BML Handle.

3.1 Preparation

Equipment and Personal Protective Equipment

Prepare all equipment and personal protective equipment which will be used with the instrument and BML Handle in accordance with their respective instruction manuals. Appropriate personal protective equipment may include: Eye wear, a face mask, moisture-resistant clothing and chemical-resistant gloves.

Spare Instrument and BML Handle

Always have a spare instrument and BML Handle available.

Sterilized Syringe and Contrast Medium for Inspection

Prepare a sterile syringe and contrast medium for inspection.

Reprocessing Equipment

Prepare reprocessing equipment as described in Section 5.2, “Required Reprocessing Equipment” for immediate reprocessing after use.

Equipment to be Used in Emergency

Always have pliers ready to cut the Coil Sheath, Tube Sheath and/or Basket Wire in case lithotripsy cannot be performed. Also have the Olympus Lithotriptor BML-110A-1 ready.

3.2 Inspection

Wear the personal protective equipment as specified in the Table on page 59.

Before each case, always inspect the instrument and the BML Handle according to the following procedures.
If an abnormality in the instrument or the BML Handle is detected, use a spare instrument or BML Handle, inspecting it thoroughly before use.

Inspection of the Sterile Package

Inspect the sterile package for tears, inadequate sealing or water damage. If the sterile package shows any irregularities, the sterile condition of the instrument or the BML Handle may have been compromised. Use a spare instead.

Appearance Inspection

If any of following steps reveals irregularities, do not use the instrument or the BML Handle; use a spare instead.

WARNING Before use, carefully inspect the entire coil sheath as instructed in this chapter; confirm that it is not crushed, bent, deformed or otherwise damaged. A damaged coil sheath may not be able to properly crush a calculus and/or it could cause the instrument to break.

Inspecting the Instrument

WARNING Be sure to inspect the Coil Sheath before assembly. Never attempt to use the instrument if you suspect that the Coil Sheath has an irregularity or is damaged. If an instrument in this condition is used, it may malfunction or cause patient injury, such as punctures, hemorrhages or mucous membrane damage. Equipment damage and performance deterioration may also result.

CAUTION When pulling the Basket Wire out of the Protective Tube, take care not to bend the Pipe of the Basket Wire. This could damage the Basket Wire.

1. Straighten the Protective Tube containing the Basket Wire. Then, hold the Basket Tip and withdraw the Basket Wire all the way. Dispose of the Protective Tube. (See Figure 3.1)

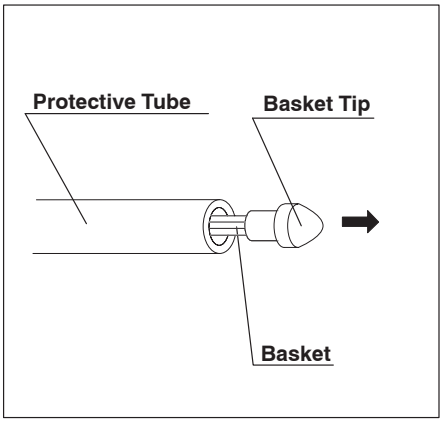


Figure 3.1

NOTE

Do not withdraw the Basket Wire forcibly if the Wire Joint catches on the Protective Tube. Use your fingers to gently extricate the part of the Basket Wire that is caught and then withdraw it.

2. Confirm that the Coil Sheath, Tube Sheath and Basket Wire are free from disconnection or looseness.
3. Gently run your fingertips over the entire length of the Coil Sheath and Tube Sheath to check for any crushed areas, excessive bends, etc..
4. Confirm that there is no unraveled, disconnected or broken wires, sharp protrusions, sharp edges or any other apparent abnormalities of the Basket Wire.

❍ Inspecting the BML Handle

Make sure that there are no cracks on the BML Handle.

Assembling and Inspection

CAUTION

- Do not use excessive force when assembling the instrument. This could damage the instrument.
- Be sure to keep the Coil Sheath and Tube Sheath straight when assembling the instrument. If the Coil Sheath or Tube Sheath is not straight, the instrument could be damaged.
- Move the Basket Wire's Pipe back and forth slowly. Fast or abrupt movement could damage the Pipe.

1. Straighten the Tube Sheath.
2. Insert the Basket Wire into the proximal end of the Tube Sheath as shown in Figure 3.2.

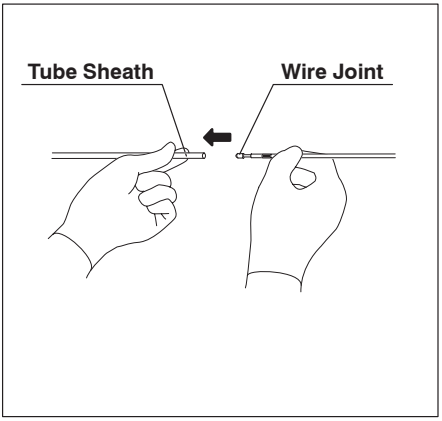


Figure 3.2

NOTE The Basket Wire's Pipe bends easily. Use extra care when handling it.

3. Extend the Wire Joint from the Stopper on the proximal end of the Tube Sheath as shown in Figure 3.3.

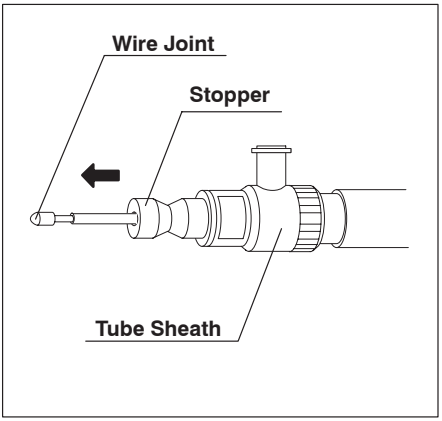


Figure 3.3

NOTE

Force is sometimes required to extend the Wire Joint from the Stopper on the proximal end of the Tube Sheath. If this is the case, do not try to insert the Wire Joint forcibly. Keep the insertion portions of the Coil Sheath and Tube Sheath as straight as possible.

4. Withdraw the Pipe from the Stopper until the Basket is completely closed.
5. While operating the Pipe to open and close the Basket, confirm that the Basket Wire is free from disconnection or looseness.
6. Open the Basket. Make sure that there are no unraveled, disconnected or broken Wires, sharp protrusions, sharp edges or any other apparent abnormalities.
7. Make sure that there are no excessive bends, sharp edges or other apparent deformations in the Pipe of the Basket Wire.
8. Confirm that the distal end of the Basket Wire appears exactly as shown in the Table in Section 2.2 “Specifications” and is not damaged.

Making and Inspecting the Connections

WARNING

- Make sure the screw is tightened. If not securely tightened, the pipe may disattach, the basket may not to be moved, and/or the calculus may not be crushed.

- Make sure to have the stopper and the BML handle connected. If the instrument separates from the BML handle during operation, the pipe may break or become uncontrollable. Also, this instrument with calculus engaged may not be removed from the body.

CAUTION

- Do not hold the BML Handle by the Holder if the Tube Sheath's Stopper is not connected. The weight of the instrument could bend the Basket Wire.
- Make sure that the Tube Sheath's Stopper is securely attached to the BML Handle. If the BML Handle's Holder is extended when the Handle is not attached firmly, the instrument may become detached and the Basket Wire could be damaged.
- When connecting the BML Handle with the Wire Joint, fully unlock the Button on the Handle's Holder by turning the Screw. If the Button is pressed before the Screw is completely unlocked, the Basket Wire may come off from the BML Handle, and it may lead to malfunctioning of the handle or breakage of the Wire Joint.

NOTE

The Screw on the BML Handle may be locked so that the Button cannot be pressed by mistake, which would cause the Basket Wire to be disconnected.

If any of following steps reveals irregularities, do not use the instrument or the BML Handle; use a spare instead.

1. Turn the Screw on the BML Handle counterclockwise to unlock the Button. (See Figure 3.4)

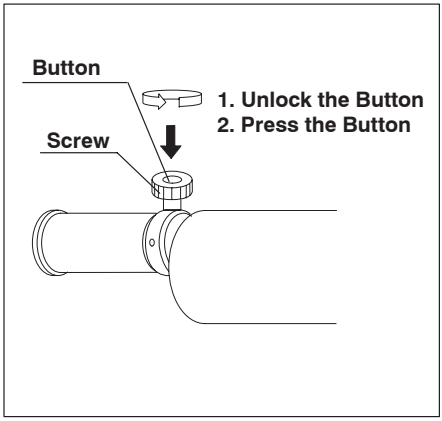


Figure 3.4

2. Loosen the Clamping Screw of the BML Handle by turning it counterclockwise until it stops.
3. Push the Holder of the BML Handle as far as it can go.
4. Insert the Basket Wire's Pipe into the BML Handle's Insertion Hole as far as it can go. (See Figure 3.5)

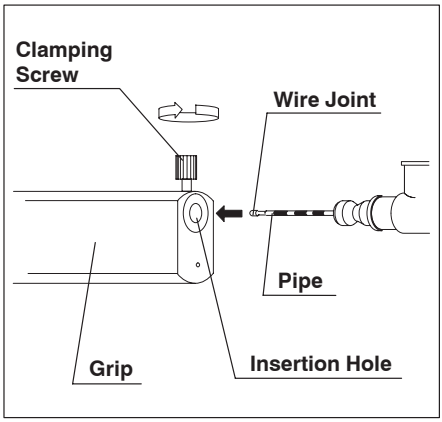


Figure 3.5

5. After completing Step 4., press the Button on the BML Handle's Holder (See Figure 3.4). While pressing the Button, insert the Basket Wire's Pipe further into the Insertion Hole until it stops. (See Figure 3.5)

6. Release the Button when the Pipe can be inserted no further.

7. Confirm that Wire Joint of Basket is visible Wire through the Slit (See Figure 3.6). Then, push and pull the Basket Wire's Pipe to make sure that the Wire Joint is securely attached to the Holder.

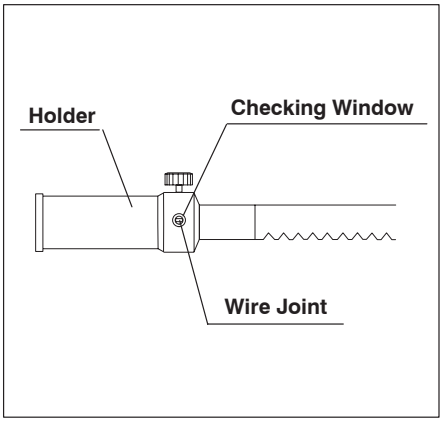


Figure 3.6

8. Insert the Tube Sheath's Stopper as far as possible into the BML Handle's Insertion Hole.
(See Figure 3.7)

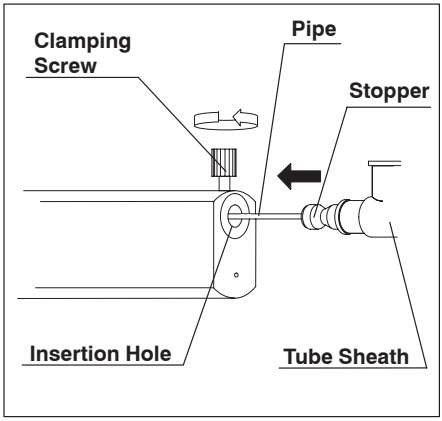


Figure 3.7

9. Tighten the BML Handle's Clamping Screw by turning it clockwise until it stops. (See Figure 3.7)

10. Turn the Screw on the BML Handle clockwise to lock the Button. (See Figure 3.8)

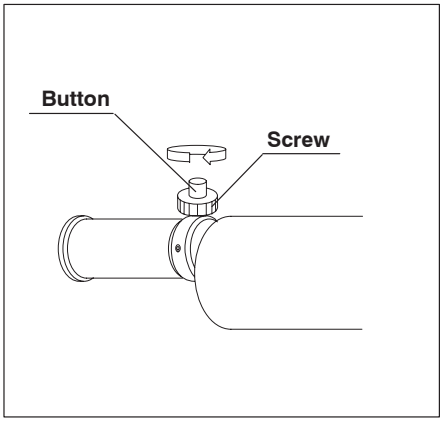


Figure 3.8

11. Push and pull the Slide Region of the Coil Sheath to make sure the Tube Sheath's Stopper is securely attached to the BML Handle.

Inspection of Operation

WARNING After assembly, check that no abnormality is detected in the action of the handle. If there is any abnormality, the calculus may not be crushed and/or the instrument with stone engaged may not be removed from the body.

If the instrument does not operate smoothly and as intended, do not use the instrument or the BML Handle; use a spare instead.

1. Holding the instrument and the BML Handle as shown in Figure 3.9, form a loop in the Insertion Portion approximately 20 cm in diameter.

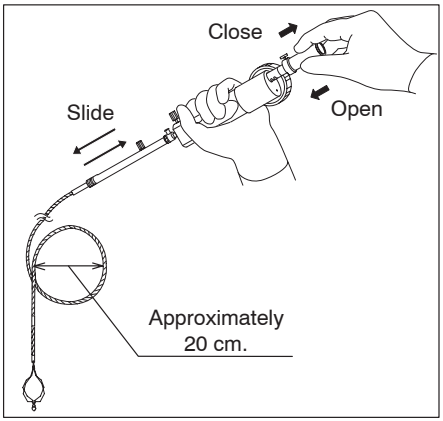


Figure 3.9

2. Operate the Holder and confirm that the Basket opens and closes smoothly.
3. Move the Coil Sheath's Knob back and forth to make sure that it slides smoothly.

4. Move the Coil Sheath's Knob until it sits in the groove nearest to the Identification Mark. Make sure that the Tube Sheath does not extend from the distal end of the Coil Sheath.

Inspecting Irrigation

Perform the following inspection only when using the BML-3Q-1. Irrigation inspection is not necessary when using the BML-4Q-1.

NOTE The BML-4Q-1 is not designed for injection of a contrast medium.

Do not use the instrument if the contrast medium cannot be injected or if it leaks from any area other than the distal end. In this case, use a spare instead.

WARNING Use a contrast medium intended for patient use when inspecting irrigation. Other fluids may remain inside the channel and pose an infection control risk and/or cause tissue irritation.

1. Open the Basket and inject a contrast medium into the instrument's Port using a sterile syringe. Confirm that the contrast medium only comes out of the distal end of the instrument. (See Figure 3.10)

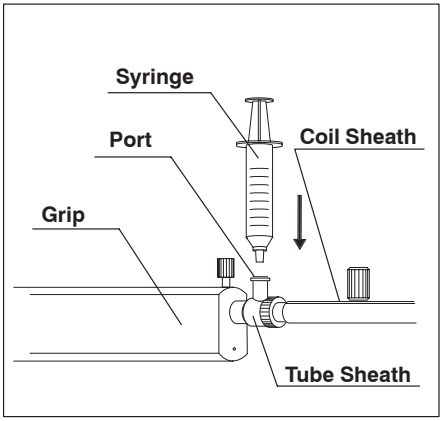


Figure 3.10

2. Make sure that the contrast medium does not leak from any area other than the distal end of the instrument.
3. Connect a sterile syringe to the instrument's Port. Inject air into the Insertion Portion to discharge the contrast medium.

3.3 Operation

The operator of the instrument and the BML Handle must be a physician or medical personnel under the supervision of a physician and must have received sufficient training in clinical endoscopic technique.
This manual, therefore, does not explain or discuss clinical endoscopic procedures. It only describes basic operation and precautions related to the operation of this instrument and BML Handle.

WARNING

- Operation of this instrument is based on the assumption that open surgery is possible as an emergency measure. In the course of crushing a hard calculus, the pipe and/or the basket wire could break and fall off of the instrument inside the patient. If the pipe or basket wire is damaged during use, immediately stop using the instrument and follow the appropriate instruction(s) given in Chapter 4, “Emergency Treatment”.
- Do not insert the instrument into the endoscope unless you have a clear endoscopic field of view. If you cannot see the distal end of the Insertion Portion in the endoscopic field of view or in X-ray images, do not use it. This could cause patient injury, such as punctures, hemorrhages or mucous membrane damage. It may also damage the endoscope and/or instrument.
- Do not angulate the Bending Section of the Endoscope or operate the Forceps Elevator abruptly while the distal end of the Insertion Portion is extended from the Distal End of the endoscope. This could cause patient injury, such as punctures, hemorrhages or mucous membrane damage.
- Do not force the distal end of the Insertion Portion against body cavity tissue. This could cause patient injury, such as punctures, hemorrhages or mucous membrane damage.

Inserting Into the Endoscope

WARNING

- Do not insert the instrument into the endoscope, if the Basket is not completely retracted into the Insertion Portion. The distal end of the Insertion Portion may extend from the Distal End of the endoscope tip abruptly. This could cause patient injury, such as punctures, hemorrhages or mucous membrane damage. It may also damage the endoscope and/or instrument.
- When inserting the instrument into the endoscope, raise the Forceps Elevator to its maximum height. If the Forceps Elevator is down, you will not be able to see the distal end of the Insertion Portion in the endoscopic field of view. This could cause patient injury, such as punctures, hemorrhages or mucous membrane damage.
- When inserting the instrument into the endoscope, hold the Holder firmly. Otherwise, the Basket may extend from the Distal End of the endoscope abruptly. This could cause patient injury, such as punctures, hemorrhages or mucous membrane damage. It may also damage the endoscope and/or instrument.

- Do not force the instrument, if resistance to insertion is encountered. Reduce the angulation or lower the Forceps Elevator of the endoscope until the instrument passes smoothly. This could cause patient injury, such as punctures, hemorrhages or mucous membrane damage. It may also damage the endoscope and/or instrument.
- Do not advance or extend the instrument abruptly. This could cause patient injury, such as punctures, hemorrhages or mucous membrane damage. It could also damage the endoscope and/or instrument.

CAUTION

- When inserting the instrument into the endoscope, hold it close to the Biopsy Valve and keep it as straight as possible relative to the Biopsy Valve. Otherwise, the Insertion Portion could be damaged.
- Insert the instrument slowly. Abrupt insertion may damage the endoscope and/or instrument.

1. Raise the Forceps Elevator to its maximum height.
2. Loosen the Coil Sheath's Knob by turning it clockwise and slide the Knob toward the proximal end until it stops as shown in Figure 3.11. Tighten the Knob to secure it in position.

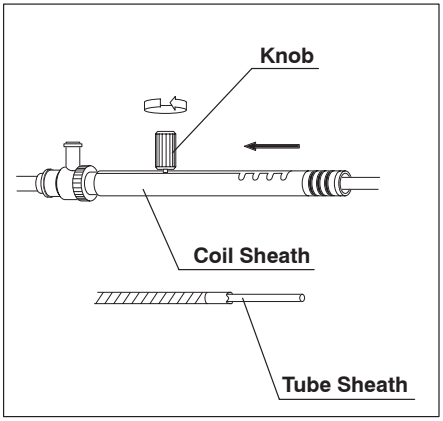


Figure 3.11

3. Retract the Basket into the Tube Sheath.

4. With the Basket retracted, carefully insert the instrument into the Biopsy Valve of the endoscope. (See Figure 3.12)

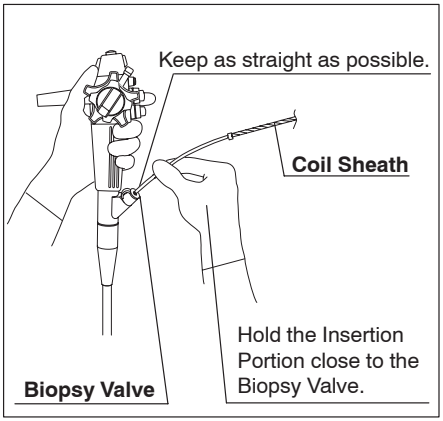


Figure 3.12

5. When the distal end of the Insertion Portion contacts the Forceps Elevator, lower the Forceps Elevator.

6. Advance the instrument another 20 mm and raise the Forceps Elevator. You will see the distal end of the instrument in the endoscopic field of view.

Inserting Into the Bile Duct

WARNING Do not forcibly insert the Insertion Portion into the Bile Duct. This could cause patient injury, such as punctures, hemorrhages or mucous membrane damage.

Insert the distal end of the instrument into the bile duct via the opening in the duodenal papilla.

NOTE If resistance is too strong and insertion of the instrument is difficult, lower the Forceps Elevator and move the distal end of the instrument slightly forward. Then raise the Forceps Elevator.

Grasping

WARNING

- Do not withdraw this instrument with stone engaged from the bile duct abruptly and/or with excessive force. This could cause punctures, hemorrhages, mucous membrane damage or edema.
- Do not push the Holder abruptly, as it may cause the Basket to open abruptly. This could cause patient injury, such as punctures, hemorrhages or mucous membrane damage. It could also damage the endoscope and/or instrument.

- When the lithotriptor's basket does not smoothly open or close, do not apply force but move the forceps elevator or the scope's angle back, or move the position of the basket until the basket opens or closes with ease. If the action is forced, the tube may stretch and cannot be stored inside the coil sheath. Also, the calculus may not be crushed, and/or the instrument with calculus engaged may not be removed from the body.

CAUTION

- Do not grasp calculi forcibly as this could deform the distal end of the Tube Sheath. This could damage the instrument.
- Do not open and close the Basket too quickly. Doing so could damage the instrument.

1. To grasp the target calculi, angulate the endoscope and/or advance the instrument required distance.
2. Push the Holder to open the Basket.
3. Surround the target calculus, with the open Basket.
4. Pull the Holder to grasp the target calculis.

Crushing the Calculi

WARNING

- This instrument will deform and/or deteriorate by performing lithotripsy. When lithotripsy is repeated, it will deform and/or deteriorate furthermore. By such deformation and/or deterioration, calculus may not be crushed and/or the instrument with calculus engaged may not be removed from the body. If lithotripsy is required to be repeated in a single case, make sure to check each time that no abnormality is found in action and/or appearance (e.g. basket wire cut or worn, tube sheath bent, notable coil sheath bent or gap etc.). Stop use when any abnormality is detected.
- If resistance is too great and it is difficult to slide the Coil Sheath, adjust the angulation of the endoscope until the Coil Sheath slides smoothly. Forcible sliding may cause the distal end of the Coil Sheath to extend abruptly. This could cause patient injury, such as punctures, hemorrhages or mucous membrane damage. It may also damage the endoscope and/or instrument.
- During lithotripsy, keep the portion; from the coil sheath to the BML handle, straight in line with the scope's biopsy valve, as much as possible. If not straight, the coil sheath may bend, calculus may not be crushed, and/or the instrument with calculus engaged may not be removed from the body.

- Do not rotate the BML handle knob abruptly. This instrument may break, and/or calculus may not be crushed. Also, the instrument with calculus engaged may not be removed from the body.
- Lower the endoscope's forceps elevator when performing lithotripsy. If lithotripsy is performed when the elevator is not lowered, the scope or the instrument may break and/or the calculus may not be crushed. Also, the instrument with calculus engaged may not be removed from the body.
- Do not forcibly push or pull the instrument or the BML Handle during lithotripsy. This could cause patient injury, such as punctures, hemorrhages or mucous membrane damage. It may also damage the endoscope and/or instrument.
- During lithotripsy, make sure to have the knob of the coil sheath properly set in the groove of the slider part. If the coil sheath moves, the stone may not be crushed and/or the instrument with calculus engaged may not be removed from the body.
- Do not push the BML handle's holder forcibly when the basket does not open after crushing the calculus. As it may cause the basket to open abruptly. This could cause patient injury, such as punctures, hemorrhages or mucous membrane damage. It could also damage the endoscope and/or instrument.

- When making the coil sheath slide, confirm under X-ray image that the tube sheath is completely covered by coil sheath. If not completely covered, the calculus may not be crushed and/or the instrument with calculus engaged may not be removed from the body.

CAUTION While rotating the Knob, it will generate resistance in the opposite direction. Do not loosen your grip because the Knob could create friction that could hurt your hand.

1. Lower the Forceps Elevator.
2. Loosen the Knob on the Coil Sheath.
3. While gently inserting the Coil Sheath, slowly move the Knob as shown in Figure 3.13.

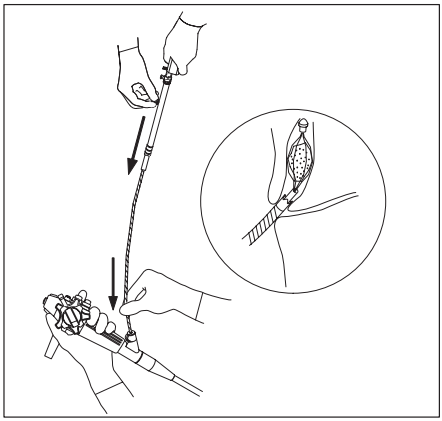


Figure 3.13

NOTE

The operation shown in Figure 3.13 requires coordination between the operator and assistant. Practice this operation before actually performing it on a patient.

4. While observing the X-ray image, move the distal end of the Coil Sheath in front of the calculus. Cover the Tube Sheath completely with the Coil Sheath. Then, set the Knob in the groove nearest possible to the Identification Marks, and tighten the Knob.
(See Figure 3.14)

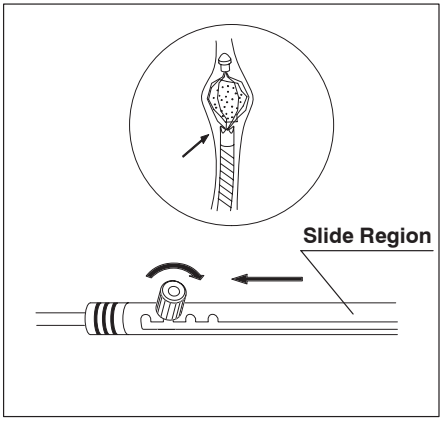


Figure 3.14

5. Make sure that the Knob is firmly attached to the Slide Region.

6. Without releasing the calculus, turn the Rotatable Knob on the BML Handle in the direction of arrow. This will cause the Basket to squeeze the calculus, crushing it.

NOTE

- The Basket Wire, Coil Sheath and/or Tube Sheath may become deformed when strong force is used to crush a calculus. In this case, replace the deformed Basket Wire, Coil Sheath or Tube Sheath with a spare.
- To prevent damaging the instrument, the Rotatable Knob on the BML Handle can be turned even when the Holder is fully extended. At this point, the Basket cannot be pulled in any further. If this condition occurs, stop turning the Rotatable Knob.

Withdrawing the Instrument From the Endoscope

WARNING

- Do not withdraw the instrument abruptly from the bile duct. It could cause mucous membrane damage or edema.
- Do not withdraw the instrument from the endoscope quickly. This could scatter blood, mucous or other patient debris and pose an infection control risk.

CAUTION

- Do not withdraw the instrument from the endoscope if the Basket is not completely retracted into the Tube Sheath. This could damage the endoscope and/or instrument.
- Do not withdraw the instrument from the endoscope if the Forceps Elevator is up. This could damage the endoscope and/or instrument.

1. Pull the Holder to retract the Basket into the Tube Sheath.

2. Withdraw the instrument from the endoscope.

Detaching

WARNING Do not pull the Basket Wire from the Tube Sheath quickly. Do not pull the Tube Sheath from the Coil Sheath quickly. This could scatter blood, mucous or other patient debris and pose an infection control risk.

1. Loosen the Clamping Screw on the BML Handle by turning it counterclockwise and remove the Coil Sheath and Tube Sheath.
2. Turn the Screw on the BML Handle counterclockwise to unlock the Button.
3. Firmly press the Button on the BML Handle and remove the Basket Wire.
4. Straighten the Insertion Portions of the Coil Sheath and the Tube Sheath. While holding the Basket Tip, withdraw the Basket Wire from the Tube Sheath.
5. Loosen the Fixing Screw on the Coil Sheath and withdraw the Tube Sheath from the Coil Sheath.

Disposal of Used Basket Wire

WARNING

- After use, dispose of the Basket Wire in an appropriate manner. If it is not properly disposed of, it could pose an infection control risk.
- Do not reuse the Basket Wire. Reusing the Basket Wire could pose an infection control risk, cause tissue irritation or malfunction.

After using the Basket Wire, dispose of it in an appropriate manner.

Chapter 4 Emergency Treatment

4.1 Emergency Treatment

If lithotripsy can no longer be performed, follow the procedures described in this Chapter. If there is little resistance from the BML Handle's Rotatable Knob, the instrument may be damaged and lithotripsy may not be possible.

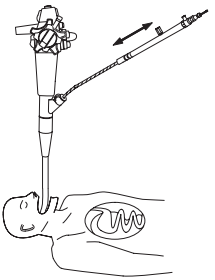
CAUTION If the calculus is too hard and the Lithotriptor is damaged as described on pages 46 – 51, it may be necessary to use the BML-110A-1. In this case, also refer to the instruction manual for the BML-110A-1.

1. Loosen the Clamping Screw on the BML Handle by turning it counterclockwise, and remove the Coil Sheath and Tube Sheath.
2. Turn the Screw on the BML Handle counterclockwise to unlock the Button.
3. Firmly press the Button on the BML Handle, and remove the Basket Wire.
4. Perform the appropriate treatment given on the charts on Pages 46 through 51.

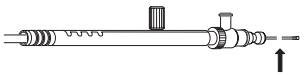
When the Pipe is Fractured.

When the Pipe can be moved.

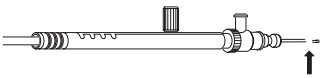
Move the Basket back and forth to release the calculus.



When the Pipe is fractured.



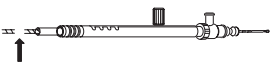
fractured here.



fractured here.

When the Pipe cannot be moved.

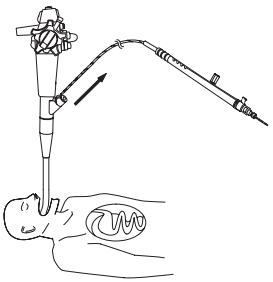
Cut the Coil Sheath, Tube Sheath and Basket Wire using pliers or wire cutters.



Cut

When the calculus can be released.

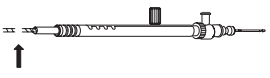
Remove the instrument from the endoscope.



Dispose of the Basket Wire and carefully inspect the Coil Sheath and Tube Sheath.

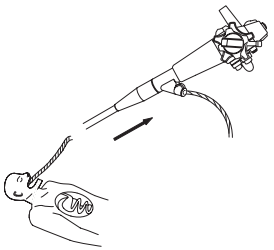
When the calculus cannot be released.

Cut the Coil Sheath, Tube Sheath and Basket Wire using pliers or wire cutters.



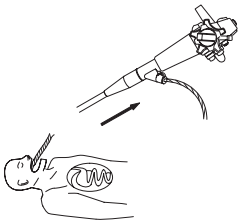
Cut.

Withdraw the Coil Sheath, Tube Sheath and endoscope together.



Use the Olympus's lithotriptor BML-110A-1 or carry out open surgery or other possible treatment.

Withdraw the endoscope.



A certain amount of force is sometimes required to withdraw the endoscope.

When the Coil Sheath and Tube Sheath can be moved.

Withdraw the Coil Sheath and Tube Sheath.

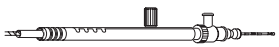
Use the Olympus's lithotriptor BML-110A-1 or carry out open surgery or other possible treatment.

When the Coil Sheath and Tube Sheath cannot be moved.

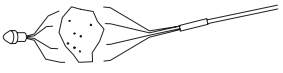
Carry out open surgery or other possible treatment.

When the Pipe is not Fractured.

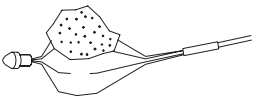
When the Pipe is not fractured.



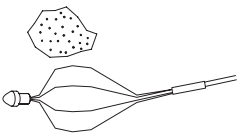
All four wires on the Basket have broken and the Basket Tip has become separated.



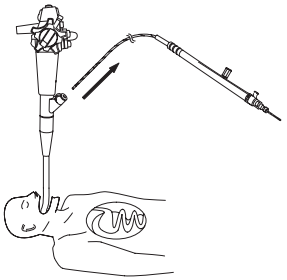
Some of the wires on the Basket have been broken.



The calculus is not inside the Basket and the instrument is not broken.



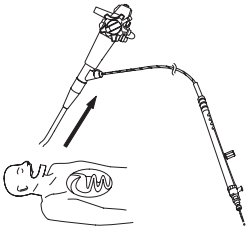
After retracting the Basket Wire into the Tube Sheath, withdraw the instrument.



WARNING Do not withdraw the instrument or its fall-offs of the instrument from the bile duct with excessive force. This could cause punctures, hemorrhages, mucous membrane damage or edema.

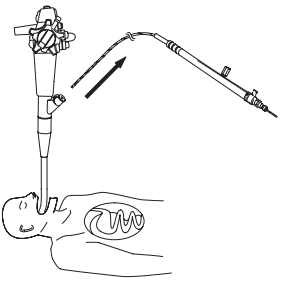
Carry out open surgery or other possible treatment.

WARNING If the broken wires of the Basket Wire cannot be retracted into the Tube Sheath, do not withdraw the instrument and endoscope with excessive force. This could cause patient injury, such as punctures, hemorrhages or mucous membrane damage.



Retract the Basket Wire into the Tube Sheath, then retract Tube Sheath into the endoscope. Then withdraw the endoscope and instrument together.

Withdraw the instrument.



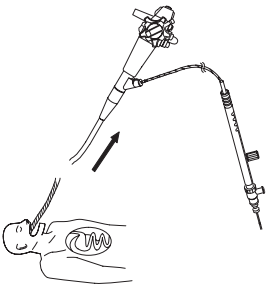
Dispose of the Basket Wire and carefully inspect the Coil Sheath and Tube Sheath.

When the Pipe Does not Extend From the Proximal End of the Tube Sheath.

When the Pipe does not extend from the proximal end of the Tube Sheath.

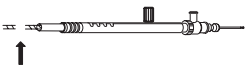
When the Coil Sheath can be moved forward or back with respect to the endoscope.

Withdraw the Coil Sheath, Tube Sheath and endoscope together.



When the Coil Sheath cannot be moved forward or back with respect to the endoscope.

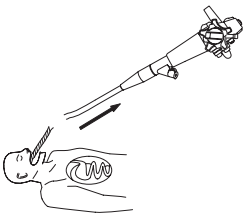
Cut the Coil Sheath, Tube Sheath and Basket Wire using pliers or wire cutters.



Cut

Use the Olympus's lithotriptor BML-110A-1 or carry out open surgery or other possible treatment.

Withdraw the endoscope.



A certain amount of force is sometimes required to withdraw the endoscope.

When the Coil Sheath and Tube Sheath can be moved.

Withdraw the Coil Sheath and Tube Sheath.

Use the Olympus's lithotriptor BML-110A-1 or carry out open surgery or other possible treatment.

When the Coil Sheath and Tube Sheath cannot be moved.

Carry out open surgery or other possible treatment.

When to use the BML-110A-1

WARNING

- Before use, thoroughly review the method of use for lithotriptor BML-110A-1 in accordance with the instruction manuals.
- Do not use this lithotriptor BML-110A-1 for a calculus that is assumed impossible to be crushed by this lithotriptor. The basket wire etc. may break and part of this lithotriptor may remain in the body.
- Use this instrument by having the settings to switch to open surgery and the hospitalization plan ready in case the calculus cannot be crushed by lithotriptor BML-110A-1.
- Operation of Mechanical Lithotriptor BML-110A-1 is based on the assumption that open surgery is possible as an emergency measure. If the calculus is too hard and the Basket Wire or Mechanical Lithotriptor is damaged, lithotripsy cannot be continued. Use the BML-110A-1 with the understanding that its could become damaged Basket Wire and that open surgery may have to take place.

If the calculus is too hard, it is possible that the damages shown below (See Figures 4.1, 4.2 and 4.3) and other damages may occur. In addition, before using BML-110A-1, thoroughly review the manual of BML-110A-1 and use the instruments as instructed.

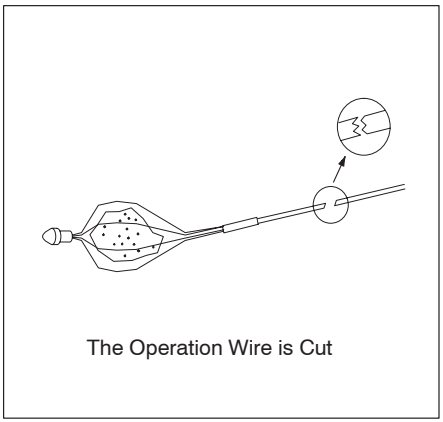


Figure 4.1

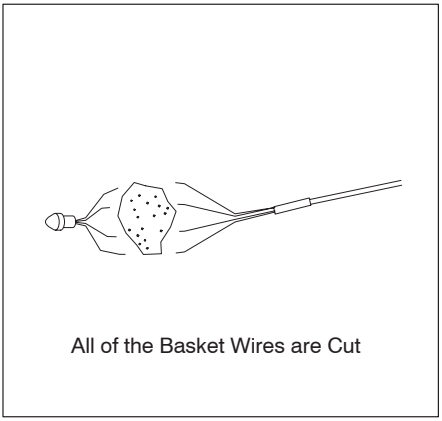


Figure 4.2

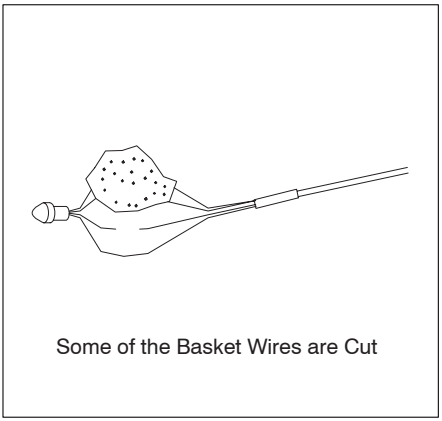


Figure 4.3

Chapter 5 Reprocessing

WARNING

- The Coil Sheath, the Tube Sheath and the BML Handle were not sterilized before shipment. Before using the Coil Sheath, the Tube Sheath and the BML Handle for the first time, reprocess them according to the instructions in this Chapter.
  Do not use the BML Handle that has not been cleaned and sterilized. This poses an infection control risk and/or can cause tissue irritation.
- The Basket Wire is single-use, disposable item that is not to be reprocessed. Do not reuse or attempt to sterilize it after use. This could pose an infection control risk and/or cause tissue irritation.

5.1 General Policy

- The medical literature reports incidents of patient cross contamination resulting from improper cleaning or sterilization. It is strongly recommended that reprocessing personnel have a thorough understanding of and follow all national and local hospital guidelines and policies.
  A specific individual or individuals in the endoscopy unit should be responsible for reprocessing endoscopic equipment. It is highly desirable that a trained backup be available should the primary reprocessing individual(s) be absent.
- All individuals responsible for reprocessing should thoroughly understand:

- your institution's reprocessing procedures
- occupational health and safety regulations
- all national and local hospital guidelines and policies
- the instructions in this manual
- the mechanical aspects of endoscopic equipment
- pertinent germicide labeling

WARNING

- Failure to properly clean and sterilize the Coil Sheath, the Tube Sheath and the BML Handle after each examination can compromise patient safety. During use, the instrument normally comes in contact with intact mucous membranes. To minimize the risk of transmitting diseases from one patient to another, after each examination the instrument and the BML Handle must undergo thorough cleaning followed by sterilization.
- If the Coil Sheath, the Tube Sheath or the BML Handle is not cleaned meticulously, effective sterilization cannot be obtained. Clean the Coil Sheath, the Tube Sheath and the BML Handle thoroughly before sterilization to remove microorganisms or organic material which can limit the effectiveness of the sterilization process.

- Patient debris and reprocessing chemicals are hazardous. Wear personal protective equipment to guard against dangerous chemicals and infectious material. During cleaning and sterilization, always wear appropriate personal protective equipment, such as eye wear, a face mask, moisture-resistant clothing and chemical-resistant gloves that fit properly and are long enough so that your skin is not exposed. Always remove contaminated protective clothing before leaving the reprocessing area.
- The reprocessing procedures described in this manual should be completed the same day the Coil Sheath, the Tube Sheath and the BML Handle have been used. If reprocessing is delayed, residual organic debris will solidify and it may be difficult to effectively reprocess the Coil Sheath, the Tube Sheath and/or the BML Handle.
- With the cleaning and sterilization methods stated in this instruction manual, prions, which are considered to be the pathogenic substance of the Creutzfeldt-Jakob disease (CJD) cannot be destroyed or inactivated. When using this instrument on a patient with CJD or variant Creutzfeldt-Jakob disease (vCJD), be sure to use this product for such patient only and/or immediately dispose of this product after use in an appropriate manner. For methods to handle CJD, please follow the respective guidelines in your country.

- This instrument is not durable, or does not have sufficient durability against the respective methods stated in the guidelines of each country for destroying or inactivating prions. For information on the durability against each method, please contact Olympus. If cleaning and sterilization methods not stated in this instruction manual are performed, Olympus cannot guarantee the effectiveness, safety and durability of this instrument. Make sure to confirm that there is no abnormality before use, and use under responsibility of a physician. Do not use if any abnormality is found.

NOTE

Olympus Endo-Therapy Accessories are compatible with 2.0% to 3.2% glutaraldehyde solutions. However, routine biological monitoring is not feasible with glutaraldehyde and, therefore, it should not be used to sterilize reusable medical devices that are compatible with other methods of sterilization that can be biologically monitored, such as steam sterilization.

5.2 Required Reprocessing Equipment

Wear the personal protective equipment as specified in the Table on page 59.

1. Prepare the following equipment. The required amount of detergent solution, lubricant and other equipment depends on the number of Coil Sheaths, Tube Sheaths and BML Handles to be reprocessed.
2. Fill an immersion basin with detergent solution and fill a second immersion basin with lubricant at the temperatures and concentration recommended by the manufacturer. Also fill the ultrasonic cleaner with a detergent solution appropriate for ultrasonic cleaning.

Equipment Needed for Reprocessing

To perform proper reprocessing, the equipment in the following table is required. For details on preparation and directions for use of the following equipment, refer to the respective instruction manuals or contact the equipment manufacturer.

Contact Olympus for the names of specific brands of detergent solutions and lubricants.

Equipment Needed

Protective Equipment	Appropriate personal protective equipment may include: eye wear, face mask, moisture-resistant clothing and chemical-resistant gloves.
Immersion Basin for Detergent Solution	Use a basin with a depth and diameter large enough to allow complete immersion of the instrument when the Insertion Portion is coiled with a diameter of not less than 15 cm.

Detergent Solution for Immersion	Use a neutral pH, low-foaming, medical-grade detergent solution.
10 cm^3 (10 ml) syringe	
Ultrasonic Cleaner	Use a medical-grade ultrasonic cleaner with a frequency range of 38 to 47 kHz, and with a depth and a diameter large enough to allow complete immersion of the instrument when the Insertion Portion is coiled with a diameter of not less than 15 cm. Compatible ultrasonic cleaner includes OLYMPUS ULTRASONIC CLEANER KS-2.
Detergent Solution for Ultrasonic Cleaning	Use a neutral pH, low-foaming, medical-grade detergent solution with no abrasive.
Immersion Basin for Lubricant	Use a basin with a depth and diameter large enough to allow complete immersion of the instrument when the Insertion Portion is coiled with a diameter of not less than 15 cm.
Lubricant	Use a medical-grade, water soluble or low-viscosity emulsion type lubricant. A high viscosity lubricant will be difficult to inject into the Port.
Lint-free Cloths	
Packages for Steam Sterilization	Use packages compatible with steam sterilization (autoclaving). The packages should be large enough to accommodate the instrument when the Insertion Portion is coiled with a diameter of not less than 15 cm. The packages should be large enough to contain the BML Handle.
Sealing Device for Sterile Packages	Sealing the packages may require a device such as a heat sealer. Prepare an appropriate sealing device according to the packages to be used.
Autoclave	Use an autoclave that will operate at the conditions specified in Section 5.6, “Sterilization”

5.3 Cleaning

WARNING When cleaning, avoid exposure to the fluids discharged from the Insertion Portion and reprocessing chemicals. They may pose an infection control risk or cause skin irritation.

CAUTION

- When reprocessing, do not coil the Insertion Portion with a diameter of less than 15 cm. This could damage the Insertion Portion.
- Never use excessive force to open or close the Coil Sheath, the Tube Sheath or the BML Handle. This could damaged the Coil Sheath, the Tube Sheath and/or BML Handle.

Immersion

WARNING

- Do not withdraw the Tube Sheath from the Coil Sheath quickly. This could scatter blood, mucous or other patient debris and pose an infection control risk.
- Immerse the Coil Sheath, the Tube Sheath and the BML Handle in detergent solution immediately after use. If the Coil Sheath, the Tube Sheath or the BML Handle is not cleaned immediately, it may be difficult to effectively reprocess, and this could result in reduced performance.

1. Immerse the Insertion Portion of the Tube Sheath in the detergent solution.
2. Connect a 10 cm^3 (10 ml) syringe filled with detergent solution to the Port.
3. Cover the Stopper's opening with your finger and Inject 10 cm^3 (10 ml) of detergent solution into the Insertion Portion. (See Figure 5.1)
   If it is not possible to inject the detergent solution or if it leaks from any areas other than the distal end of the Insertion Portion, do not use the Tube Sheath.
4. Disconnect the syringe from the Port.

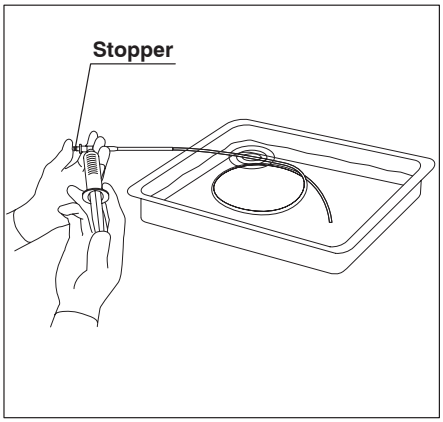


Figure 5.1

5. Fully immerse the BML Handle in the detergent solution. Make sure that the Rotatable Knob is facing up. (See Figure 5.2)

6. Immerse the entire the Coil Sheath, the Tube Sheath and the BML Handle in the detergent solution for the time specified in manufacturer's instructions. If no time is specified, immerse for between 5 minutes and 3 hours.

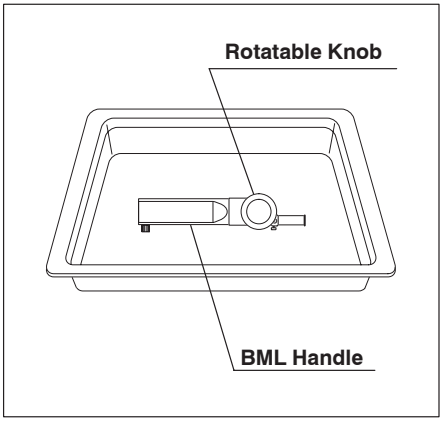


Figure 5.2

7. Remove the Coil Sheath, the Tube Sheath and the BML Handle from the detergent solution.

8. Put the Holder of the BML Handle downwards, and discharge the remaining detergent solution from the Outlet. Then, push and pull the Holder two or three times. (See Figure 5.3)

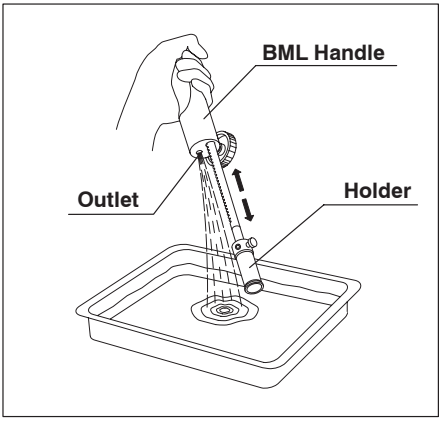


Figure 5.3

Ultrasonic Cleaning

1. Immerse the distal end of the Tube Sheath in the ultrasonic cleaner containing detergent solution.
2. Connect a 10 cm^3 (10 ml) syringe filled with detergent solution to the Port.
3. Cover the Stopper's opening with your finger and Inject 10 cm^3 (10 ml) of detergent solution into the Insertion Portion. If it is not possible to inject the detergent solution or if it leaks from any area other than the distal end of the Tube Sheath, do not use the Tube Sheath.

NOTE

Even if the same type of detergent solution is used for both immersion and ultrasonic cleaning, make sure to inject detergent solution at this time. Replacing the detergent solution inside the Insertion Portion will increase the effectiveness of cleaning.

4. Disconnect the syringe from the Port.
5. Immerse the entire Coil Sheath, Tube Sheath and BML Handle in the detergent solution. Make sure the Rotatable knob is forcing up. (See Figure 5.2)
6. Clean ultrasonically for 30 minutes. For details on operation of the ultrasonic cleaner, refer to the instruction manual of the ultrasonic cleaner.
7. Remove the Coil Sheath, the Tube Sheath and the BML Handle from the detergent solution.
8. Put the Holder of the BML Handle downwards, and discharge the remaining detergent solution from the Outlet. Then, push and pull the Holder two or three times. (See Figure 5.3)

Rinsing

CAUTION

- After ultrasonic cleaning, rinse the Coil Sheath, the Tube Sheath and the BML Handle thoroughly to remove residual detergent. Residual detergent solution could cause tissue irritation in the next patient.
- Do not forcefully squeeze, wipe or scrub the Coil Sheath, the Tube Sheath and the BML Handle. This could cause damage to the Coil Sheath, the Tube Sheath and/or the BML Handle result in reduced performance.

1. Connect a 10 cm^3 (10 ml) syringe filled with clean tap water to the Port.
2. Cover the Stopper's opening with your finger and Inject 10 cm^3 (10 ml) of water into the Tube Sheath. If it is not possible to inject water or if it leaks from any area other than the distal end of the Tube Sheath, do not use the Tube Sheath.
3. Disconnect the syringe from the Port.
4. Repeat Steps 1. through 3. to inject a total of 20 cm^3 (20 ml) of water into the Tube Sheath.
5. Rinse the Coil Sheath, the Tube Sheath and the BML Handle under clean running tap water.
6. Push and pull the Holder two or three times under clean running tap water.
7. Confirm that no debris is left on the surfaces of the Coil Sheath, the Tube Sheath.
8. Push and pull the Holder and confirm that no debris remains on the other surface of the BML Handle.
9. Connect a 10 cm^3 (10 ml) syringe filled with air to the Port.

10. Cover the Stopper's opening with your finger and Inject 10 cm^3 (10 ml) of air into the Tube Sheath.
11. Disconnect the syringe from the Port.
12. Repeat Steps 9. through 11. until no liquid comes out of the distal end of the Tube Sheath.
13. Wipe the exterior of the Coil Sheath, the Tube Sheath and the BML Handle with a clean, dry lint-free cloth.

5.4 Lubrication

WARNING When lubricating, avoid exposure to the fluids discharged from the Insertion Portion and lubricant. It may pose an infection control risk and/or cause skin irritation.

CAUTION Do not coil the Insertion Portion with a diameter of less than 15 cm. This could damage the Insertion Portion.

1. Immerse the entire Coil Sheath and the BML Handle in the lubricant for 2 to 3 seconds.
2. Connect a 10 cm^3 (10 ml) syringe filled with lubricant to the Port.
3. Cover the Stopper's opening with your finger and inject the lubricant until it comes out of the distal end. If it is not possible to inject the lubricant or it leaks from any area other than the distal end of the Tube Sheath, do not use the Tube Sheath.
4. Disconnect the syringe from the Port.
5. Connect a 10 cm^3 (10 ml) syringe filled with air to the Port.
6. Cover the Stopper's opening with your finger and inject 10 cm^3 (10 ml) of air into the Tube Sheath once.

7. Disconnect the syringe from the Port.
8. Repeat steps 5. through 7. until no lubricant comes out of the distal end of the Tube Sheath.
9. Loosen the Knob on the Slide Region of the Coil Sheath. Then move the Knob back and forth to slide the Slide Region a few times.
10. Remove the BML Handle from the lubricant. Put the Holder of the BML Handle downwards, and discharge the remaining lubricant from the Outlet. Then, push and pull the Holder two or three times.
(See Figure 5.3)
11. Wipe the exterior of the Coil Sheath, the Tube Sheath and the BML Handle with a clean, dry lint-free cloth and allow them to air dry.

5.5 Assembly

Inspection Before Assembly

WARNING Be sure to inspect the Coil Sheath and the Tube Sheath before assembly. Never attempt to use the instrument if you suspect that the Coil Sheath and the Tube Sheath has an irregularity or is damaged. If an instrument in this condition is used, it may malfunction or cause patient injury, such as punctures, hemorrhages or mucous membrane damage. Equipment damage and performance deterioration may also result.

CAUTION To avoid damaging the Coil Sheath, the Tube Sheath or the BML Handle, do not use excessive force when handling them.

Inspect the instrument and the BML Handle according to the following procedure. If an abnormality is detected, do not use the instrument or the BML Handle. Use a spare instead.

1. Confirm that the Coil Sheath and Tube Sheath are free from disconnection or looseness.
2. Gently run your fingertips over the entire length of the Coil Sheath and Tube Sheath to check for any crushed areas, excessive bends, etc..
3. Gently run your fingertips over the entire length of the Tube Sheath to check for broken areas, etc..

Assembly

CAUTION

- Do not use excessive force when assembling the Coil Sheath and the Tube Sheath. This could damage the Coil Sheath and the Tube Sheath.
- Be sure to keep the Coil Sheath and Tube Sheath straight when assembling the Coil Sheath and the Tube Sheath. If the Coil Sheath or Tube Sheath is not straight, the Coil Sheath and the Tube Sheath could be damaged.

1. Loosen the Knob on the Coil Sheath and slide it as far as possible toward the proximal end. Then tighten the Knob to fix the position of the Slide Region. (See Figure 5.4)

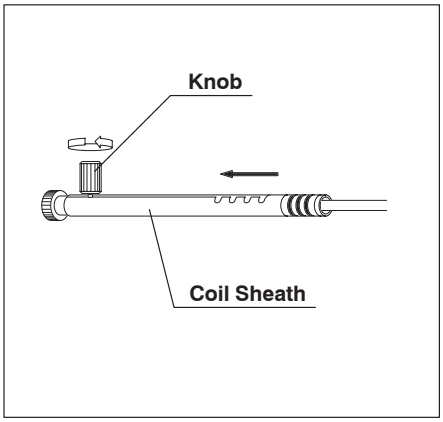


Figure 5.4

2. Straighten the Coil Sheath.

3. Insert the Tube Sheath into the proximal end of the Coil Sheath as shown in Figure 5.5.

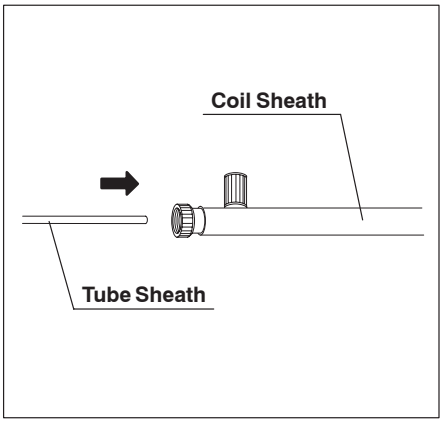


Figure 5.5

NOTE

- The Tube Sheath may get caught inside the Coil Sheath when it is inserted. If this happens, do not try to insert the Tube Sheath forcibly. Instead, pull or turn the Tube Sheath gently to make it easier to insert.
- The connection of the Guide Pipe and the Tube of the Tube Sheath is very fragile. Use extra care when handling it.

4. Align the guide pin of the Tube Sheath with the Notch at the proximal end of the Coil Sheath as shown in Figure 5.6. Tighten the Fixing Screw to secure them.

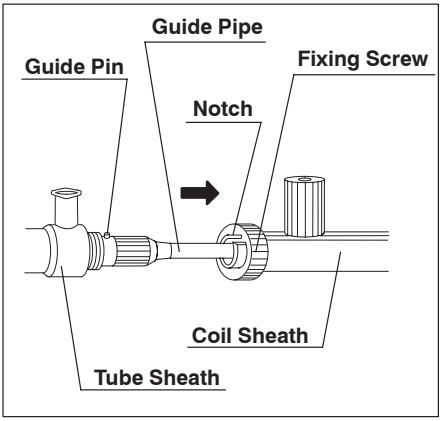


Figure 5.6

5. Make sure that the Tube Sheath is extended from the distal end of the Coil Sheath.

5.6 Sterilization

Sealing the Package

CAUTION

- Do not coil the Coil Sheath, the Tube Sheath with a diameter of less than 15 cm. This could damage the instrument.
- Seal the Coil Sheath, the Tube Sheath and the BML Handle in separate packages. Otherwise, they could be damaged.

1. Before sterilization, the Coil Sheath, the Tube Sheath and the BML Handle must be thoroughly cleaned and dried. Residual moisture inhibits sterilization.
2. Coil the Coil Sheath, the Tube Sheath and place it in the package.
3. Place the BML Handle in a separate package.
4. Seal the packages. For details on sealing, refer to the instruction manual of the packages and the sealing device.

Steam Sterilization (Autoclaving)

WARNING

- Use biological indicators as recommended by your hospital's policy and follow the manufacturer's instructions, all national and local hospital guidelines and policies.
- Always leave space between the packages in the autoclave. If the packages are placed too close together, effective sterilization will not be possible.

- Allow the sterile packages to dry within the autoclave using the autoclave's drying cycle (if applicable) or by opening the door of the autoclave and allowing the packages to air dry. Handling a wet package can compromise its sterility.
- The results of sterilization depend on various factors such as how the sterilized instrument was packed or the positioning, method of placing and loading of the instrument in the sterilization device. Please verify the sterilization effects by using biological or chemical indicators. Also follow the guidelines for sterilization issued by medical administrative authorities, public organizations or the infection management sections at each medical facility, as well as the instruction manual of the sterilization device.

1. Place the sealed packages containing the Coil Sheath, the Tube Sheath and the BML Handle in the autoclave and sterilize in accordance with the conditions listed below. For details on operation of the autoclave, refer to the instruction manual for the autoclave or other manufacturer instructions.
2. After steam sterilization, let the Coil Sheath, the Tube Sheath and the BML Handle gradually cool down to room temperature. Sudden changes in temperature may damage the Coil Sheath, the Tube Sheath and/or the BML Handle.

NOTE

Autoclavable products have a green reference label. Products that do not have green reference labels are not autoclavable.

	Temperature	Exposure Time
Prevacuum	132 to 134°C (270 to 274°F)	5 minutes

Table 5.1 Recommended Steam Sterilization (Autoclaving) Conditions

Chapter 6 Storage

WARNING

- Do not store the Coil Sheath, the Tube Sheath or BML Handle in a sterile package that is damaged, wet or improperly sealed. Otherwise, the sterility of the Coil Sheath, the Tube Sheath or BML Handle may be compromised and pose an infection control risk and/or cause tissue irritation.
- Do not store sterile packages containing the Coil Sheath, the Tube Sheath or BML Handle in place where they will be damaged, wet or improperly sealed. Otherwise, the sterility of the Coil Sheath, the Tube Sheath or BML Handle may be compromised and pose an infection control risk and/or cause tissue irritation.

CAUTION

Do not coil the Coil Sheath, the Tube Sheath with a diameter of less than 15 cm. This could damage the instrument.

6.1 Inspection Before Storage

Prior to storage, inspect the sterile packages as follows:

1. Confirm that the sterile package containing the Basket Wire is free from tears, inadequate sealing or water damage. If tears, inadequate sealing or water damage is detected, do not use the instrument; contact Olympus.
2. Confirm that the sterile packages containing the Coil Sheath, the Tube Sheath and the BML Handle are free from tears, inadequate sealing or water damage. If tears, inadequate sealing or water damage is detected, repackage and sterilize again as described in Section 5.6, “Sterilization”.

6.2 Storage

Store the instrument and the BML Handle in the sterile packages at room temperature in a clean and dry environment. Do not store it in direct sunlight. Ensure that the packaged instrument and the BML Handle are not crushed by surrounding objects during storage. Follow any additional storage instruction provided by the manufacturer of the sterile package.

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